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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,461	12/11/2003	Michael P. Czech	UMY-055	3119
959	7590	12/22/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			ASHEN, JON BENJAMIN	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,461

Applicant(s)

CZECH ET AL.

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005 and 03 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27, 38-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 27, 38-81 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claim 27, in the reply filed on 08/01/2005 is acknowledged. However, the requirement for restriction as set forth in the Action mailed 07/01/2005 is hereby withdrawn. The following new requirement for restriction is set forth and is necessitated by Applicant's supplemental amendment to claim 27 and addition of new claims 38-81, in the communication filed 10/03/05.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 38-49, 51-59, 79 and 81, drawn to a method of identifying a gene that affects glucose transport comprising contacting an adipocyte with an siRNA targeted against a gene and assaying the modulation of glucose transport in the cell wherein glucose transport is assayed by assaying insulin mediated glucose uptake, classifiable in class 424, subclass 9.2.
- II. Claims 38-48, 50-59, 79 and 81, drawn to a method of identifying a gene that affects glucose transport comprising contacting an adipocyte with an siRNA targeted against a gene and assaying the modulation of glucose transport in the cell wherein glucose transport is assayed by assaying insulin mediated GLUT4 translocation, classifiable in class 424, subclass 9.2.

III. Claims 61-72, 74-78 and 80-81, drawn to a method of identifying a gene that affects glucose transport comprising contacting an adipocyte with a nucleic acid molecule that is capable of expressing an siRNA targeted against a gene and assaying the modulation of glucose transport in the cell wherein glucose transport is assayed by assaying insulin mediated glucose uptake, classifiable in class 424, subclass 9.2.

IV. Claims 61-71, 73-78 and 80-81, drawn to a method of identifying a gene that affects glucose transport comprising contacting an adipocyte with an siRNA targeted against a gene and assaying the modulation of glucose transport in the cell wherein glucose transport is assayed by assaying insulin mediated GLUT4 translocation, classifiable in class 424, subclass 9.2.

3. Claims 27 and 81 link(s) inventions I and II. Claims 60 and 81 link(s) inventions III and IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 27, 60 or 81. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or

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divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other because of the following reasons:

5. The inventions of Groups I-IV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The inventions of groups I-IV are all drawn to methods of identifying a gene that affects glucose transport wherein each invention is a patentably distinct method that is carried out with a different mode of operation, i.e., is practiced using different method steps. Invention I is distinguished from Invention II by mode of operation which is by the distinct step of assaying insulin mediated glucose vs. assaying GLUT4 translocation. Inventions III and IV are likewise distinguished. Inventions I and II are distinguished from inventions III and IV by the requirement, of inventions I and II, for contacting the adipocyte with an siRNA, a nucleic acid molecule that is a double stranded RNA and that is structurally and functionally distinct from a nucleic acid molecule that is capable of expressing a dsRNA molecule, especially in the absence of any particular and claimed nucleotide sequences. The vector encoding the siRNA, as set forth in claims

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60 and 80, is not required to encode the siRNA that is required by the method set forth and claimed in claims 27 and 79 and is distinguished from siRNAs by function, which is to express a given nucleotide sequence, and by mode of operation, which requires expression not required by the siRNA set forth in claim 27.

Furthermore, searching any of the inventions of groups I-IV together would impose a serious and undue search burden. In the instant case, prior art searches of the instantly claimed methods would not be coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would necessarily include a search for the particular method steps required by each invention and/or the particular structural requirements of the siRNAs or nucleic acid molecules that express siRNAs, that are required by the instant methods, would not be required in a search of the other methods. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of any of the inventions of groups I-IV together.

6. Claim 81 is generic to a plurality of disclosed patentably distinct species of method that identify a gene involved in a insulin response disease or disorder wherein the disease or disorder is selected from the group consisting of Type II diabetes, insulin resistance and obesity. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 517-272-0811811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba

Jane Zarn
TC1600